IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICALS U.S.A., INC., Plaintiff, v. PAR PHARMACEUTICAL COMPANIES, INC., and PAR PHARMACEUTICAL, INC., Defendants.	Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Takeda Pharmaceuticals U.S.A., Inc. ("Takeda") files this Complaint for patent infringement against Defendants Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. (collectively "Par") and, in support thereof, alleges as follows.

NATURE OF THE ACTION

1. This is an action for patent infringement under the Food and Drug and Patent Laws of the United States, U.S.C. Titles 21 and 35 respectively, arising from Par's submission of an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA"), seeking approval to sell commercially a generic version of the drug product COLCRYS® (colchicine, USP) prior to the expiration of United States Patent Nos. 7,906,519, 7,935,731, 8,093,298, 7,964,648, and 8,093,297 which cover, *inter alia*, COLCRYS® for the use of treating Familial Mediterranean Fever.

THE PARTIES

2. Takeda Pharmaceuticals U.S.A., Inc. is a Delaware corporation with its principal place of business at One Takeda Parkway, Deerfield, IL 60015. Takeda holds all right, title and interest in each patent asserted in this action.

3. On information and belief, Par Pharmaceutical Companies, Inc. ("Par Pharma") is a Delaware corporation with its principal place of business at One Ram Ridge Road, Spring Valley, NY 10977 and is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States.

4. On information and belief, Par Pharmaceutical, Inc. ("Par Pharma, Inc.") is a Delaware corporation with its principal place of business at One Ram Ridge Road, Spring Valley, NY 10977 and is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States.

5. Upon information and belief, Par Pharma, Inc. is a wholly-owned subsidiary of and serves as the generic drug division for Par Pharma.

6. Upon information and belief, the acts of Par Pharma, Inc. complained herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of, Par Pharma.

JURISDICTION AND VENUE

7. This Court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and 1338(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

8. This Court has personal jurisdiction over Par Pharma because, among other reasons, it is a Delaware corporation, has extensive contacts with the State of Delaware, and regularly does business in this district by selling generic pharmaceutical products. Upon

information and belief, Par Pharma has previously consented to the personal jurisdiction of this Court on multiple occasions and has previously availed itself of this Court by filing suit and asserting counterclaims in other civil actions initiated in this jurisdiction (*See, e.g.*, Civ. A. No. 07-414-JJF).

9. This Court has personal jurisdiction over Par Pharma, Inc. because, among other reasons, it is a Delaware corporation, has extensive contacts with the State of Delaware, and regularly does business in this district by selling generic pharmaceutical products. Upon information and belief, Par Pharma, Inc. has previously consented to the personal jurisdiction of this Court on multiple occasions and has previously availed itself of this Court by filing suit and asserting counterclaims in other civil actions initiated in this jurisdiction.

10. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

COLCRYS®

11. COLCRYS® is used to treat, *inter alia*, Familial Mediterranean Fever ("FMF"). FMF is a rare, autosomal recessive, auto-inflammatory disease characterized by recurrent and/or chronic inflammation. COLCRYS® is the only single active ingredient oral colchicine product approved by the FDA treat FMF.

12. As part of the FDA approval for COLCRYS®, Takeda received Orphan Drug exclusivity which expires July 29, 2016.

13. In 2009, as a result of extensive research by Mutual Pharmaceutical Company ("Mutual" – a former affiliate of Takeda), the FDA for the first time approved an oral single active ingredient colchicine product: COLCRYS®. Through its groundbreaking research, Mutual discovered important new information about colchicine, including previously unknown

information concerning safety and efficacy, tolerability, dangerous side effects, and interactions with other medicines and substances.

14. The FDA approved COLCRYS® for marketing in the United States under New Drug Application ("NDA") Nos. 22-351, 22-352, and 22-353, pursuant to section 505(b) of the Federal Food Drug and Cosmetics Act ("FFDCA"), 21 U.S.C. § 355(b).

THE COLCRYS® PATENTS

15. Takeda is the lawful owner of all right, title, and interest in and to the following United States patents, including the right to sue and to recover for infringement thereof, which patents contain one or more claims covering methods of using COLCRYS®.

A. United Sates Patent Number 7,906,519 ("the '519 Patent"), entitled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," a copy of which is attached hereto as Exhibit A and incorporated herein by reference as though set forth in full, which was duly and legally issued March 15, 2011, naming Matthew Davis as the inventor.

B. United States Patent Number 7,935,731 ("the '731 Patent"), entitled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND MACROLIDE ANTIBIOTICS," a copy of which is attached hereto as Exhibit B and incorporated herein by reference as though set forth in full, which was duly and legally issued May 11, 2011, naming Matthew Davis as the inventor.

C. United States Patent Number 8,093,298 ("the '298 Patent"), entitled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A MACROLIDE ANTIGIOTICS," a copy of which is attached hereto as Exhibit C and

incorporated herein by reference as though set forth in full, which was duly and legally issued January 10, 2012, naming Matthew Davis as the inventor.

D. United States Patent Number 7,964,648 ("the '648 Patent"), entitled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," a copy of which is attached hereto as Exhibit D and incorporated herein by reference as though set forth in full, which was duly and legally issued June 21, 2011, naming Matthew Davis as the inventor.

E. United States Patent Number 8,093,297 ("the '297 Patent"), entitled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," a copy of which is attached hereto as Exhibit E and incorporated herein by reference as though set forth in full, which was duly and legally issued January 10, 2012, naming Matthew Davis as the inventor.

16. The '519, '731, '298, '648 and '297 Patents are collectively referred to herein as the "Patents."

17. The Patents are listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book"), maintained by the FDA as a patent "with respect to which a claim of patent infringement could be reasonably asserted if a person not licensed by the owner engaged in the manufacture, use or sale of the drug." 21 U.S.C. § 355(b)(1).

PAR'S ACTIONS GIVING RISE TO THIS SUIT

18. In December 2011, Par submitted ANDA No. 203976 to the FDA seeking approval to engage in the commercial use, manufacture, sale, offer to sell or importation of 0.6

mg oral colchicine tablets ("Par's Proposed Product") prior to the expiration of the Takeda's patent rights.

19. On or about February 23, 2012, Takeda received a letter dated February 21, 2012, and signed by a representative of Par, purporting to be notice of Par's filing of ANDA No. 203976 seeking approval to engage in the commercial use, manufacture, sale, offer to sell or importation of Par's Proposed Product and allegedly containing a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") required by 21 U.S.C. § 355(j)(2)(b)(i) and (ii), with respect to, inter alia, the '648 and '297 Patents. (Par's "First Paragraph IV Notice Letter"). The stated purpose of the letter was to notify Takeda that Par had filed a certification under 21 C.F.R. § 314.95 in conjunction with its ANDA for approval to engage in the commercial use, manufacture, sale, offer to sell or importation of Par's Proposed Product for the treatment and prevention of gout flares. Par asserted in its First Paragraph IV Notice Letter that the '648 and '297 Patents are invalid or would not be infringed with respect to the treatment and prevention of gout flares and that Par was not seeking FDA approval for the treatment of FMF indication based on a so called "carve out" pursuant to §355(j)(2)(A)(viii).

20. On or about March 15, 2012, Takeda received a letter dated March 13, 2012, and signed by a representative of Par, purporting to be notice of Par's filing of ANDA No. 203976 seeking to engage in the commercial use, manufacture, sale, offer to sell or importation of Par's Proposed Product and allegedly containing a Paragraph IV Certification required by 21 U.S.C. § 355(j)(2)(b)(i) and (ii), with respect to, inter alia, the '648 and '297 Patents (Par's "Second Paragraph IV Notice Letter"). The stated purpose of the letter was to notify Takeda that Par had filed a certification under 21 C.F.R. § 314.95 in conjunction with its ANDA for approval to engage in the commercial use, manufacture, sale, offer to sell or importation of Par's Proposed

Product for the treatment and prevention of gout flares. Par asserted in its Second Paragraph IV Notice Letter that the '648 and '297 Patents are invalid or would not be infringed with respect to the treatment and prevention of gout flares and that Par was not seeking FDA approval for the treatment of FMF based on a so called "carve out" pursuant to §355(j)(2)(A)(viii).

21. After reviewing Par's First and Second Paragraph IV Letters, and within 45 days of receipt of Par's letters, Takeda filed a lawsuit against Par Pharma, Inc. in this District alleging, *inter alia*, that pursuant to 35 U.S.C. § 271, Par had committed an act of infringement by submitting an ANDA with a Paragraph IV certification seeking approval to engage in the commercial use, manufacture, sale, offer to sell or importation of Par's Proposed Product for the treatment and prevention of gout flares prior to expiration of Takeda's '648 and '297 Patents (*See* Civ. A. No. 12-419 (SLR)).

22. At some time after being sued for infringement in this District for submitting ANDA No. 203976, Par voluntarily elected to abandon its request for FDA approval with respect to the treatment and prevention of gout flares.

23. On or about July 22, 2013, Takeda received a letter dated July 19, 2013, and signed by a representative of Par, purporting to be notice of the filing of ANDA No. 203976 seeking to engage in the commercial use, manufacture, sale, offer to sell or importation of Par's Proposed Product and allegedly containing a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) required by 21 U.S.C. § 355(j)(2)(b)(i) and (ii), with respect to the Patents. ("Par's Third Paragraph IV Notice Letter"). The stated purpose of the letter was to notify Takeda that Par had filed a certification under 21 C.F.R. § 314.95 in conjunction with its ANDA for approval to seek approval to engage in the commercial use, manufacture, sale, offer to sell or importation of Par's Proposed Product for the treatment of FMF. Par's Third Paragraph IV

Notice Letter alleges that Takeda's Patents listed in the Orange Book covering the use of COLCRYS® to treat FMF are invalid and/or will not be infringed by commercial use or sale of Par's Proposed Product.

24. Par's Third Paragraph IV Notice Letter further informed Takeda that its proposed labeling does not include dosing instructions or safety information for the treatment or prevention of gout flares.

25. Par recently submitted a label amendment to the FDA such that the proposed label originally submitted with ANDA No. 203976 was being amended for the purpose of limiting FDA approval of its Proposed Product to the treatment of FMF and that pursuant to §355(j)(2)(A)(viii), Par seeks to carve out from the FDA-approval COLCRYS® label, *inter alia*, information regarding the treatment and prevention of gout flares, including all dosing instructions for the treatment and prevention of gout flares.

26. Takeda's FDA approved product label for COLCRYS® contains, *inter alia*, methods of using COLCRYS® as disclosed and claimed in the Patents, including the use of colchicine to treat FMF when a patient is or is not taking another substance.

27. Under the FFDCA, drug products submitted to the FDA for approval via an ANDA are required to have the same labeling as the reference listed drug, here COLCRYS®, except for changes required because of differences approved under a suitability petition (21 U.S.C. § 355(j)(2)(c); 21 C.F.R. § 314.93) or because the generic drug product and reference listed drug are produced or distributed by different manufacturers (21 U.S.C. § 355(j)(2)(A)(v); 21 C.F.R. §314.94(a)(8)(iv)).

28. If Par's generic colchicine product is approved by the FDA, Par will infringe and/or induce others to infringe one or more claims of the Patents.

29. Upon information and belief, Par has made, and continues to make, substantial preparation in the United States for the commercial manufacture, use, offer to sell, sale, and/or importation of its Proposed Product prior to Takeda's Patents expiry.

30. Par's actions, including, but not limited to, the development of its Proposed Product and the filing of ANDA No. 203976 with a Paragraph IV certification, indicate a refusal to change the course of its actions despite its knowledge of Takeda's unexpired Patents.

31. Upon information and belief, Par continues to seek approval of ANDA No. 203976 from the FDA to engage in the commercial use, manufacture, sale, offer to sell or importation of its Proposed Product for the treatment of FMF prior to the expiry of Takeda's Patents.

32. Takeda commenced this action within 45 days of receiving Par's Third Paragraph IV Notice Letter.

COUNT I

(Infringement of the '519 Patent)

33. Paragraphs 1 to 32 are incorporated herein as set forth above.

34. Par has committed an act of infringement of the '519 Patent that creates a justiciable case or controversy between Takeda and Par.

35. Par's submission of its ANDA No. 203976 to seek approval to engage in the commercial use, manufacture, sale, offer to sell or importation of Par's Proposed Product to treat FMF prior to expiration of the '519 Patent constitutes infringement of one or more claims of the '519 Patent under 35 U.S.C. § 271(e)(2)(A).

36. Unless enjoined by the Court, upon FDA approval of ANDA No. 203976 and expiration of Takeda's Orphan Drug exclusivity, Par will induce infringement of the '519 Patent

under 35 U.S.C. § 271(b) by making, using, importing, selling, and offering to sell Par's Proposed Product in the United States. On information and belief, upon approval of ANDA No. 203976 and expiration of Takeda's Orphan Drug exclusivity, Par will intentionally encourage acts of direct infringement immediately by healthcare providers administering and/or patients using Par's Proposed Product with knowledge of the '519 patent and knowledge that its acts are encouraging infringement.

37. Takeda will be irreparably harmed by Par's infringing activities unless those activities are enjoined by this Court.

38. Takeda does not have an adequate remedy at law.

39. This is an exceptional case and Takeda is entitled to an award of reasonable attorneys fees from Par.

COUNT II

(Infringement of the '731 Patent)

40. Paragraphs 1 to 39 are incorporated herein as set forth above.

41. Par has committed an act of infringement of the '731 Patent that creates a justiciable case or controversy between Takeda and Par.

42. Par's submission of its ANDA No. 203976 to seek approval to engage in the commercial use, manufacture, sale, offer to sell or importation of Par's Proposed Product to treat FMF prior to expiration of the '731 Patent constitutes infringement of one or more claims of the '731 Patent under 35 U.S.C. § 271(e)(2)(A).

43. Unless enjoined by the Court, upon FDA approval of ANDA No. 203976 and expiration of Takeda's Orphan Drug exclusivity, Par will induce infringement of the '731 Patent under 35 U.S.C. § 271(b) by making, using, importing, selling, and offering to sell Par's

Proposed Product In the United States. On information and belief, upon approval of ANDA No. 203976 and expiration of Takeda's Orphan Drug exclusivity, Par will intentionally encourage acts of direct infringement immediately by healthcare providers administering and/or patients using Par's Proposed Product with knowledge of the '731 patent and knowledge that its acts are encouraging infringement.

44. Takeda will be irreparably harmed by Par's infringing activities unless those activities are enjoined by this Court.

45. Takeda does not have an adequate remedy at law.

46. This is an exceptional case and Takeda is entitled to an award of reasonable attorneys fees from Par.

COUNT III

(Infringement of the '298 Patent)

47. Paragraphs 1 to 46 are incorporated herein as set forth above.

48. Par has committed an act of infringement of the '298 Patent that creates a justiciable case or controversy between Takeda and Par.

49. Par's submission of its ANDA No. 203976 to seek approval to engage in the commercial use, manufacture, sale, offer to sell or importation of Par's Proposed Product to treat FMF prior to expiration of the '298 Patent constitutes infringement of one or more claims of the '298 Patent under 35 U.S.C. § 271(e)(2)(A).

50. Unless enjoined by the Court, upon FDA approval of ANDA No. 203976 and expiration of Takeda's Orphan Drug exclusivity, Par will induce infringement of the '298 Patent under 35 U.S.C. § 271(b) by making, using, importing, selling, and offering to sell Par's Proposed Product In the United States. On information and belief, upon approval of ANDA No.

203976 and expiration of Takeda's Orphan Drug exclusivity, Par will intentionally encourage acts of direct infringement immediately by healthcare providers administering and/or patients using Par's Proposed Product with knowledge of the '298 patent and knowledge that its acts are encouraging infringement.

51. Takeda will be irreparably harmed by Par's infringing activities unless those activities are enjoined by this Court.

52. Takeda does not have an adequate remedy at law.

53. This is an exceptional case and Takeda is entitled to an award of reasonable attorneys fees from Par.

COUNT IV

(Infringement of the '648 Patent)

54. Paragraphs 1 to 53 are incorporated herein as set forth above.

55. Par has committed an act of infringement of the '648 Patent that creates a justiciable case or controversy between Takeda and Par.

56. Par's submission of its ANDA No. 203976 to seek approval to engage in the commercial use, manufacture, sale, offer to sell or importation of Par's Proposed Product to treat FMF prior to expiration of the '648 Patent constitutes infringement of one or more claims of the '648 Patent under 35 U.S.C. § 271(e)(2)(A).

57. Unless enjoined by the Court, upon FDA approval of ANDA No. 203976 and expiration of Takeda's Orphan Drug exclusivity, Par will induce infringement of the '648 Patent under 35 U.S.C. § 271(b) by making, using, importing, selling, and offering to sell Par's Proposed Product In the United States. On information and belief, upon approval of ANDA No. 203976 and expiration of Takeda's Orphan Drug exclusivity, Par will intentionally encourage

acts of direct infringement immediately by healthcare providers administering and/or patients using Par's Proposed Product with knowledge of the '648 patent and knowledge that its acts are encouraging infringement.

58. Takeda will be irreparably harmed by Par's infringing activities unless those activities are enjoined by this Court.

59. Takeda does not have an adequate remedy at law.

60. This is an exceptional case and Takeda is entitled to an award of reasonable attorneys fees from Par.

COUNT V

(Infringement of the '297 Patent)

61. Paragraphs 1 to 60 are incorporated herein as set forth above.

62. Par has committed an act of infringement of the '297 Patent that creates a justiciable case or controversy between Takeda and Par.

63. Par's submission of its ANDA No. 203976 to seek approval to engage in the commercial use, manufacture, sale, offer to sell or importation of Par's Proposed Product to treat FMF prior to expiration of the '297 Patent constitutes infringement of one or more claims of the '297 Patent under 35 U.S.C. § 271(e)(2)(A).

64. Unless enjoined by the Court, upon FDA approval of ANDA No. 203976 and expiration of Takeda's Orphan Drug exclusivity, Par will induce infringement of the '297 Patent under 35 U.S.C. § 271(b) by making, using, importing, selling, and offering to sell Par's Proposed Product In the United States. On information and belief, upon approval of ANDA No. 203976 and expiration of Takeda's Orphan Drug exclusivity, Par will intentionally encourage acts of direct infringement immediately by healthcare providers administering and/or patients

using Par's Proposed Product with knowledge of the '297 patent and knowledge that its acts are encouraging infringement.

65. Takeda will be irreparably harmed by Par's infringing activities unless those activities are enjoined by this Court.

66. Takeda does not have an adequate remedy at law.

67. This is an exceptional case and Takeda is entitled to an award of reasonable attorneys fees from Par.

EXCEPTIONAL CASE

68. Par was aware of the Patents before submitting a label amendment for ANDA No. 203976 to the FDA to seek approval to engage in the commercial use, manufacture, sale, offer to sell or importation of Par's Proposed Product to treat FMF.

69. Par had no basis to submit ANDA No. 203976 and or a Paragraph IV Certification. Par's actions render this an exceptional case under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Takeda requests entry of judgment in its favor and against Par as follows:

A. A judgment and decree that Par has infringed Takeda's '519, '731, '298, '648, and '297 Patents under 35 U.S.C. § 271(e)(2)(A) by submitting its ANDA No. 203976 with a Paragraph IV Certification seeking approval to engage in the commercial use, manufacture, sale, offer to sell or importation of Par's Proposed Product to treat FMF prior to the expiration of the Patents;

B. Declaring and entering judgment that Par will infringe one of more claims of the '519, '731, '298, '648, and '297 Patents under 35 U.S.C. § 271 (b) by its manufacture, use,

offering to sell, sale, and importation into the United States of its Proposed Product to treat FMF prior to the expiration of the Patents;

C. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), preliminarily and permanently enjoining Par, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from any commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States, of any drug product, including Par's Proposed Product, that infringes the '519, '731, '298, '648, and '297 Patents, including any extensions;

D. That if Par engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of its Proposed Product before the expiration of the Patents, a judgment be awarded to Takeda for damages resulting from such infringement, together with interest, in an amount to be determined at trial;

E. A judgment ordering that pursuant to 35 U.S.C. 271(e)(4)(A), the effective date of approval of ANDA 203976, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), shall not be earlier than the expiration of the '519, '731, '298, '648, and '297 Patents, including any extensions;

F. Declaring this an exceptional case under 35 U.S.C. § 285, and that Takeda be awarded reasonable attorneys' fees, costs and expenses; and

G. Such other and further relief as the Court may deem just and proper.

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Dated: August 30, 2013

WCSR 30980992v2